CHAPTER 3

Planning & Preparation

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The Council for Outbreak Response: Healthcare-Associated
Infections and Antimicrobial-Resistant Pathogens

Planning & Preparation

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Preface

Preparations made ahead of a healthcare-associated infection (HAI) or antimicrobial-resistant (AR) pathogen outbreak lay the groundwork for actions taken during the outbreak response. Activities that prepare public health agencies to respond to outbreaks involving healthcare delivery include developing the capacity to rapidly collect and analyze large amounts of information, take rapid action to stop transmission, and communicate effectively with stakeholders.

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3.0   Introduction

Adequate preparation fosters a systematic approach to HAI/AR outbreak detection and response, accelerating the evaluation of the problem and minimizing the response time. In this chapter, we lay out the roles, resources, processes, and relationships that should be in place before an outbreak is detected. Although most activities discussed in this chapter are directed toward public health agencies, other groups can also use the information provided here as a guide to understand their roles and to inform their interactions with public health.

Prior to an outbreak, public health agencies should strive to 1) engage with entities that may become partners in an outbreak response; 2) understand the roles of these partners during an outbreak; 3) develop scalable and flexible plans for all aspects of healthcare outbreak response, including the potential for incorporating an incident command system (ICS) when needed; 4) establish processes for records management and data analysis;

and 5) assemble resources and tools that can be quickly accessed and used during an outbreak response.

3.1   Agency Roles

3.1.1   Overview

Before an outbreak, public health agencies should have a clear understanding of their anticipated roles and responsibilities. Since states organize their governmental public health systems in diverse ways, the relative roles of local and state health departments will vary. In states where governance is centralized, responsibility for conducting outbreak investigations rests primarily with state health departments. Conversely, in jurisdictions where governance is decentralized ("home rule" states), this responsibility may rest primarily with the local health department.[1] Developing an understanding of individual agencies' responsibilities and establishing strong working relationships is one of the most important preparation activities for any public health agency.

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3.1.2 Local, State, and Federal Agencies

3.1.2.1 Local Public Health Agencies

Local public health agencies have extensive knowledge of local healthcare networks, providers, and facilities. As such, local public health agencies are well-positioned to actively engage partners across the continuum of care through activities such as routine surveillance of reportable conditions; bidirectional communication with healthcare organizations; hosting, attending, and presenting at meetings and educational events involving healthcare facilities and organizations; and including evaluation of the potential for HAI/AR outbreaks in annual risk assessments.

The capacities of local public health agencies vary considerably in accordance with the populations they serve—from small, rural communities to large, metropolitan areas. Local public health agencies, along with state public health agencies, have roles and responsibilities, which will be described later in this section. When resources are limited, local public health agencies should obtain support from their state public health agencies, as necessary. In some jurisdictions (for example, those with centralized governance structures), the state public health agency may already fulfill these roles.

Planning for outbreaks:

An understanding of endemic rates of disease can be helpful when planning an outbreak response. Public health agencies should establish methods for routine monitoring of baseline rates of HAIs, AR organisms, and other pathogens commonly associated with outbreaks. Local epidemiology varies across jurisdictions, and understanding local trends is necessary to determine when an outbreak may be occurring. Personnel who are responsible for performing surveillance should be trained to recognize scenarios indicating an outbreak. They should understand levels of urgency and know whom to contact when an outbreak is suspected. Local public health agencies should be aware of the local laboratory capacity and where to obtain advanced laboratory services, which may be needed to confirm outbreaks. Public health agencies should plan to engage in enhanced assessment and monitoring of infection prevention measures as part of an outbreak response.

Roles and Responsibilities:

The roles and responsibilities of local public health agencies include conducting surveillance, ensuring reporting of outbreaks by facilities within their jurisdiction, receiving and evaluating outbreak reports, providing recommendations to healthcare facilities to halt an outbreak, and notifying the public and media when warranted. Public health agencies detect HAIs, AR pathogens, and related conditions through surveillance and identify outbreaks via surveillance or receipt of outbreak reports.

Local public health agencies have a more granular view of the local population and may recognize characteristics, such as global travel patterns, that place some healthcare settings at increased risk for outbreaks. Local public health agencies may also recognize community transmission of pathogens that increase the opportunity for outbreaks within healthcare settings.

Local public health agencies should maintain a list of contacts at healthcare facilities and have a system to communicate health concerns, regularly disseminating information about local patterns of illnesses that may increase the opportunity for HAI/AR transmission in healthcare settings. Public health agencies also have the role of providing general advice to the public in their jurisdiction. Depending on resources, a local public health agency may also perform advanced laboratory testing.

Resources:

Resources of a local public health agency vary by agency but can include expertise in epidemiologic investigation, infection control, local healthcare provider outreach, and health education. The local public health agency also has a unique, in-depth knowledge of its local population, community, and healthcare facilities and organizations that is critical to leverage during an outbreak investigation and response. The local or state public health agency may serve as the coordinating agency during an outbreak investigation.

3.1.2.2 State Public Health Agencies

Compared to local public health agencies, state public health agencies generally hold a broader situational awareness of HAIs, AR pathogens, and other healthcare-

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associated pathogens across their state. Often HAI and AR pathogen surveillance is mandated at the state level, which in turn provides information to local jurisdictions and other partners. Typically, much of this surveillance activity, as well as healthcare outbreak response and HAI/AR prevention, is coordinated or conducted under the auspices of the state health department's HAI/AR program.[2,3]

Most HAI/AR programs have multidisciplinary HAI advisory groups, which include members who furnish extensive healthcare expertise, provide input on state HAI/AR action plans, and offer consultative advice to the state HAI/AR program. State HAI/AR action plans typically include outbreak detection and response activities, reflecting findings from infection control assessments conducted at healthcare facilities and lessons learned from previous outbreak investigations.

State public health agencies strive to develop engaged partnerships with organizations that facilitate information sharing at the state and federal levels (including organizations listed later in this chapter) to support outbreak detection and response. State public health agencies may advise local public health agencies during a single jurisdictional outbreak or may take a coordinating role if the local public health agency does not have jurisdiction, lacks resources, or requests this type of assistance. Multifacility and multijurisdictional HAI/AR outbreaks are typically led by state public health agencies.

Planning for outbreaks:
State public health agencies monitor baseline rates of HAIs, AR pathogens, and other healthcare-associated pathogens to understand the baseline rates of transmission and local epidemiologic trends. Similar to employees at local public health agencies, personnel at state public health agencies who are responsible for performing surveillance should recognize scenarios that may indicate an outbreak. They should understand levels of urgency and know whom to contact when an outbreak is suspected. State public health agencies should plan for notification of other agencies, healthcare facilities, and the public.

The state public health agency, working with the state public health laboratory, the Centers for Disease Control and Prevention (CDC), and/or other partners, has the ability to coordinate advanced laboratory services (e.g., next generation sequencing to determine clonality of a cluster) during outbreaks of AR pathogens and when other specialized testing is needed; it is important to maintain knowledge of which labs are available to perform advanced testing and how to interact with those laboratories to obtain testing rapidly (see Chapter 6 for more information).

Roles and Responsibilities:
The roles and responsibilities of state public health agencies are similar to those of local public health agencies, including conducting surveillance, ensuring reporting of suspected outbreaks by facilities, receiving and evaluating outbreak reports, providing recommendations to healthcare facilities to halt an outbreak, notifying the public and media when warranted, and facilitating advanced laboratory testing.

State public health agencies also set policies for HAI and AR pathogen reporting, which facilitates detection of HAIs and AR pathogens through surveillance. State public health agencies may have a greater capacity than local public health agencies to detect clusters or outbreaks using surveillance data. State public agencies also hold a key role in providing health advisories and prevention messaging to the public throughout the state.

State public health agencies may assist local public health agencies with training as part of building preparedness for outbreaks. Responsibility for coordinating or leading the investigation of more complex (e.g., multifacility and multi-jurisdictional) outbreaks often lies with the state public health agency.

Resources:
State public health agencies have expertise in epidemiologic investigation, infection control, laboratory testing, and health education, as well as other more specialized expertise (e.g., clinical, pharmacy, and antimicrobial stewardship). State public health agencies often have more resources to respond to outbreaks than local public health agencies. Clear and frequent

communication between state and local public health agencies, as well as with the healthcare provider community and other partners, fosters an effective healthcare outbreak response.

3.1.2.3 State Agencies — Healthcare Facility Survey and Licensing

The role of the state survey agency includes overseeing state-level healthcare facility licensing requirements and Medicare certifications. To accomplish this, state survey agency personnel conduct surveys (inspections) of many types of healthcare facilities to assess adherence to the minimum health and safety standards established by the Centers for Medicare & Medicaid Services (CMS) as well as to any state-specific criteria. The state survey agency may become actively involved in an outbreak response (e.g., when regulatory assistance is deemed necessary to assure compliance with infection control requirements).

State public health agencies should possess knowledge of policies and procedures for bidirectional sharing of information with the state survey agency both routinely and during an outbreak. Beginning in 2014, CMS issued expanded guidance requiring accrediting organizations and state survey agencies to report serious infection control breaches to the relevant state health department.[3] Conversely, state public health agencies should establish thresholds for the notification of the state survey agency when outbreaks are being investigated. Involving regulatory partners in outbreak response training can help clarify roles and enhance legal preparedness during an outbreak, including identifying the conditions or criteria that warrant joint investigations by the state public health agency and state survey agency.

3.1.2.4 State Agencies — Provider Licensing

The role of professional licensing agencies (e.g., medical, nursing, dental, and pharmacy licensing boards) is to oversee licensing and credentialing of healthcare providers and other licensed professionals and to ensure that competency requirements are met. State professional licensing agencies may get involved in an outbreak response when regulatory assistance is needed for situations that involve licensed healthcare providers in healthcare settings that are not licensed or Medicare-

certified at the facility level, such as a typical doctor's office or dental practice.[3] Likewise, licensing boards may receive or investigate complaints involving patient infections that could signal an outbreak, warranting attention from public health agencies.

State public health agencies should have processes in place that address bidirectional sharing of information with professional licensing agencies when needed, and thresholds and limitations for sharing this information should be established in advance. During outbreaks involving licensed healthcare providers, it can be helpful to involve professional licensing agencies if egregious practices are found or questions arise regarding a particular scope of practice, particularly when a healthcare facility is not operating as a state-licensed healthcare facility.

Involvement of the professional licensing agency can be as simple as providing information or it may rise to the level of a joint investigation. This situation is generally less common than those involving licensed healthcare facilities and, therefore, it is important for state public health agencies to have appropriate contact information and processes for contacting professional licensing boards, sharing information and conducting joint investigations when needed. As with state survey agencies, involving regulatory partners in outbreak response training can help clarify roles and enhance legal preparedness during an outbreak, including identifying conditions or criteria that may warrant joint investigations.

3.1.2.5 Federal Agencies — Centers for Disease Control and Prevention (CDC)

CDC works with public health agencies at state and local levels as well as with other federal agencies, such as the US Food and Drug Administration (FDA), to provide support during an outbreak response and to coordinate multistate outbreak investigations. CDC routinely provides consultation and laboratory assistance to healthcare facilities and health departments that are working to solve outbreaks or investigate infection control breaches and other adverse events. During some outbreak situations, CDC sends experts to work side-by-side with facility and state or local public health agency staff. For example,

state health departments may contact CDC and request assistance through a process known as an Epi-Aid.[4] Typically, these efforts include on-site assistance, laboratory support, and additional consultation with experts at CDC headquarters (see section 3.6.1 for more information).

Specific to HAI/AR surveillance, prevention, and outbreak response, CDC holds a continually active role supporting state and local public health agencies. For example, HAI/AR programs receive funding, technical assistance, and direction from CDC as part of its Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases Cooperative Agreement (ELC) with health departments. CDC also directly advises members of the public about what they can do to protect themselves, provides recommendations to the medical and public health community about how to prevent future outbreaks, and collaborates closely with policymakers, regulatory agencies, and industry to learn how to prevent outbreaks.

3.1.2.6 Federal Agencies — Food and Drug Administration (FDA)

FDA regulates and monitors the safety of drugs and medical devices. This agency conducts investigations of outbreaks suspected to be related to medical products. It is important that public health agencies and healthcare facilities notify FDA about products potentially implicated in outbreaks and that they do so early, even if the association is not yet clear. Healthcare facilities and providers can report suspected product issues to FDA via MedWatch, a voluntary web-based adverse event reporting program found at the following website: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Public health agencies can report directly to a regional FDA contact; this helps ensure that preliminary investigation findings and MedWatch reports are received and acted on in a timely manner. Determining the regional FDA contact ahead of an outbreak can facilitate timely communication. To foster bidirectional communication, state public health agencies can establish an information sharing agreement with FDA.[5] This is regulated by 21 CFR 20.88 and allows FDA to share nonpublic

information (NPI) when it is in the interest of public health. Confidential Commercial Information (CCI) about commodities regulated by FDA may be disclosed when a 20.88 agreement is in place.

3.1.3   Healthcare Facilities

Roles and Responsibilities:
Healthcare facilities have the primary responsibility for ensuring the safety of patients under their care as well as their employees and visitors. When an outbreak is suspected, facility staff have the responsibility to report the outbreak to appropriate groups within the facility (typically to the infection prevention or quality team). Additionally, the facility has the responsibility to immediately report all suspected or confirmed outbreaks to the appropriate local or state public health agency. Often the healthcare facility will begin the investigation at the same time the outbreak is reported to public health. Whereas the healthcare facility has the responsibility for ensuring the safety of patients within the facility, the public health agency has an overlapping responsibility to protect the public from disease transmission, including within healthcare facilities in their jurisdiction. It is critical that healthcare facilities and public health agencies collaborate to detect and respond rapidly to suspected outbreaks, sentinel events, and serious infection control breaches.

Within a healthcare facility, there should be at least one person designated to oversee measures to prevent transmission of infections, including the detection of and response to outbreaks. In hospitals and larger healthcare facilities, this person is usually a credentialed infection preventionist (IP); a healthcare epidemiologist and other team members may support the IP. The roles and responsibilities of this team include conducting surveillance, facilitating laboratory testing, detecting clusters, ensuring reporting of potential outbreaks internally and to public health, communicating with public health during the course of an outbreak investigation, performing investigations to understand the cause of an outbreak in collaboration with public health, implementing changes in infection prevention practices to halt an outbreak, and assisting with notifying patients or media when warranted.

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Planning for outbreaks:
Healthcare facilities should develop systems to ensure that there are adequate personnel to oversee implementation and monitor adherence to control measures in response to an outbreak. The facility IP should have completed competency-based training related to outbreak prevention and response (including auditing adherence to infection control measures, such as transmission-based precautions; staff and patient cohorting practices; and AR pathogen screening processes). The IP should establish processes for communicating with internal and external partners, including public health agencies.

Resources:
Resources within a healthcare facility to detect and respond to an outbreak vary greatly. Facilities with extensive resources and expertise in outbreak investigations may require little direct support from public health. Conversely, those lacking resources or expertise will be largely dependent on public health agencies to perform primary investigative functions. Regardless, personnel at every healthcare facility have unique, in-depth knowledge of their facility that is critical during outbreak investigation and response. Public health agencies should be prepared to work collaboratively with healthcare facilities during an outbreak response. Similarly, healthcare facilities should be prepared to assist public health with the investigation, including gathering information needed during the investigation and implementing disease control measures.

3.1.4 Patients and Other Agencies/Partners

Healthcare outbreaks primarily affect patients. Chapter 8 of the *CORHA Principles and Practices* provides detailed considerations for informing and engaging patients as part of healthcare outbreak response. Additional federal, state, territorial, tribal, local, and partner organizations, beyond the examples detailed above, may become involved in healthcare outbreak investigations. In advance of (or early in) an outbreak response, it is important to think through the array of stakeholders and partners needing to be involved or informed. Selected partners are described in this subsection in more detail, and

abbreviated information about other partners is listed in Table 3.1. Table 3.2 details partners to consider based on the type of outbreak or event.

3.1.4.1 Professional Member Organizations
Although not typically involved in outbreak detection and response directly, member organizations such as the local and national chapters of the American Professionals for Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Disease Society of America (IDSA), as well as organizations representing medical, surgical, dental, nursing, and other types of specialized healthcare professionals, can be valuable partners when public health needs to understand the local healthcare landscape and communicate to targeted groups. Organizations representing professional specialties may have their own infection control guidelines; they may also offer useful venues (conferences, journals, and websites) for outbreak investigators to reach their constituents (e.g., for assistance with case finding or to disseminate prevention messaging).

National organizations that represent healthcare facility types, such as the American Hospital Association (AHA) and the American Health Care Association (AHCA), can be helpful partners to engage for messaging and coordination at the national level. These organizations also have local chapters in some jurisdictions; forming relationships with local chapters, such as the state hospital association, healthcare association, and healthcare professional or quality improvement organizations, can improve outbreak reporting and assist communication to healthcare partners during an outbreak or a time of increased transmission of a particular infectious disease. Developing relationships with these organizations helps ensure collaboration without overlap, so that organizations and agencies can mutually support an outbreak response as well as general prevention and quality improvement efforts.

3.1.4.2 Tribal Entities and the Indian Health Service (IHS)
Tribal governments generally have complete sovereignty and autonomy over reservation lands, and nontribal

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groups can join an investigation only at the tribe's request. Investigations of outbreaks may be led by the tribal health staff, the Indian Health Service (IHS), or state health departments. Typically, public health and the IHS can implement investigation measures and control only with authorization of the tribal government.[6] Healthcare organizations operating on tribal lands have a variety of configurations.

Many healthcare facilities within tribal nations are autonomous and not bound by regulations that are applicable to other healthcare settings. Some facilities are owned by tribes and operated by the IHS, a federal agency within the US Department of Health and Human Services (HHS); other facilities are run entirely or in part by a tribal corporation that is independent of the IHS. Additional information about the IHS can be found in Table 3.1.

Engaging tribal entities as partners requires awareness of the local healthcare structure and the types of services offered. State public health agencies should develop an understanding of the structure of healthcare facilities operated by tribal entities within the state. Local healthcare providers may have the most extensive knowledge of care patterns within tribal nations and, in some cases, the local public health agency may be the most effective agency for engaging tribal partners.

3.1.4.3 Law Enforcement

Under circumstances in which criminal activity is suspected, appropriate law enforcement personnel should be notified. This may include situations in which an outbreak investigation identifies persons who are suspected of committing fraud and/or providing medical care without appropriate credentials, or persons who have stolen or tampered with controlled substances or other medications. The law enforcement agency to be notified depends on the scenario. For example, medication tampering or other aspects of drug diversion may require notification of local and state law enforcement, the Drug Enforcement Administration (DEA), and the FDA Office of Criminal Investigations (see Supplement B for more information). Public health agencies should maintain awareness of law enforcement reporting requirements; a contact list of law enforcement agencies can be developed in advance.

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
Centers for Medicare & Medicaid Services (CMS)	CMS is a federal agency that provides health coverage through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS promulgates standards, regulations, policies, and guidance (some of which pertain to infection control) that are applicable to many healthcare facilities and provider types.	CMS may report infection control breaches or suspected outbreaks to state facility licensing agencies or state public health agencies. CMS may become involved in outbreak investigations that affect Medicare-certified facilities either through the state survey agency or directly via federal surveyors or regional office staff.	CMS: www.cms.gov CMS Health and Safety Standards: www.cms.gov/medicare/health-safety-standards/conditions-coverage-participation/

Table 3.1	Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response		
AGENCY OR PARTNER	**ROLE IN OUTBREAK RESPONSE**	**EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES**	**FOR MORE INFORMATION**
Veterans Health Administration (VHA)	A federal agency and one of the largest US healthcare systems, VHA provides healthcare to US veterans. Healthcare facilities within the system function as other healthcare facilities and may investigate any healthcare-related outbreaks occurring within their system. VHA has medical epidemiologists and infection prevention professionals within their facilities.	State and local public health agencies should receive information on outbreaks directly from VHA facilities as well as information on reportable diseases and conditions for surveillance. Additional information on HAIs in VHA facilities may be available via the National Healthcare Safety Network (NHSN). Public health agencies should work with VHA facilities within their authority to investigate outbreaks.	VHA: www.va.gov/health VA Hospital Compare: www.accesstocare.va.gov/Healthcare/HospitalCompareData?s=AL&f=679&m=FLU VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs: www.va.gov/vhapublications/ CSTE position statement 16-SI-03, Veterans Health Administration Reporting of Diseases, Conditions, and Outbreaks to Local and State Public Health Authorities: https://cdn.ymaws.com/www.cste.org/resource/resmgr/2016PS/16_SI_03.pdf
Indian Health Service (IHS)	IHS is a federal agency that provides health services to members of federally recognized tribes. IHS has public health professionals on staff.	Reporting of diseases and conditions, as well as reporting of outbreaks, occurs within the IHS system. State public health agencies that have tribal lands within state borders work with IHS and tribal leaders and often collaborate on outbreak responses.[6]	IHS: www.ihs.gov/
Federal Bureau of Prisons (BOP)	BOP is a federal agency that oversees federal prisons. BOP is responsible for prisoner health, has jurisdiction over federal correctional facilities, and employs a health services division.[6]	BOP and the federal correctional facility may request public health assistance in an outbreak response, typically from CDC and/or the state public health agency.[6]	BOP: www.bop.gov

Table 3.1	Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response		
AGENCY OR PARTNER	**ROLE IN OUTBREAK RESPONSE**	**EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES**	**FOR MORE INFORMATION**
State and local correctional facilities	State and local governments run correctional facilities within their jurisdictions. They are responsible for prisoner health.[6]	State and local correctional facilities are insular, and their individual department of corrections may request public health assistance in an outbreak response.[6]	See websites for specific state departments of corrections and local correctional facilities.
US Department of Defense (DoD)	Military commanders have authority over their bases and facilities. DoD and the branch of the military involved (e.g., the Department of the Navy) has its own public health responsibilities including response to suspected outbreaks. DoD has established the position of Public Health Emergency Officer (PHEO); the person holding this job is a clinician and member of a military service medical department having relevant training in emergency management and experience in public health.[6]	If a state or local public health agency is involved in an outbreak investigation of a branch of DoD, the public health investigators must communicate and cooperate with the military base commander. The PHEO works with installation and medical treatment facility emergency managers, who also communicate with local and state health departments.[6]	DoD: www.defense.gov
US Department of the Interior	The Department of the Interior oversees and has jurisdiction over federal lands and natural resources. Scientists, including members of the Public Health Service (PHS), are employed in the National Park Service Office of Public Health.[6]	When federal lands are involved in an outbreak, state and local public health agencies should collaborate with the National Park Service Office of Public Health.[6]	Department of the Interior: www.doi.gov/ National Park Service Office of Public Health: www.nps.gov/orgs/1735/index.htm

Table 3.1 | Additional Agencies and Partners that Public Health Agencies Interact with During an Outbreak Response

AGENCY OR PARTNER	ROLE IN OUTBREAK RESPONSE	EXAMPLES OF INTERACTIONS WITH STATE AND LOCAL PUBLIC HEALTH AGENCIES	FOR MORE INFORMATION
Accrediting organizations	Accreditation is a review process of a healthcare organization performed by accrediting bodies. Accreditation is typically voluntary and allows for a demonstration of the ability to meet requirements and standards (e.g., CMS Medicare certification) and an assurance of quality for healthcare consumers and payors.	Accrediting organizations may report outbreaks or infection control breaches to CDC or state or local public health agencies.[3]	CMS quality, safety, and oversight: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/ CMS-approved accrediting organization list: www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

Table 3.2 | Partners to Consider Involving by Type of Event*

TYPE OF EVENT	AGENCIES
Single facility outbreak	Local public health agency, state public health agency, and healthcare facility/setting
Multifacility outbreak	Local public health agencies, state public health agency, and healthcare facilities/settings
Multistate outbreak	Local public health agencies, state public health agencies, healthcare facilities/settings, and CDC
Potentially contaminated medical product	Local public health agencies, state public health agencies, healthcare facilities/settings, FDA, CDC, and product manufacturer
Infection control breach in licensed healthcare setting	Local public health agency, state public health agency, state survey agency, and healthcare facility/setting
Infection control breach in private practice setting	Local public health agency, state public health agency, healthcare setting, and professional licensure board
Drug diversion (e.g., theft or tampering)	Local public health agency, state public health agency, healthcare facility/setting, professional licensure board, state survey agency, FDA, and law enforcement agencies
Outbreak related to healthcare outside the US	Local public health agencies, state public health agencies, and CDC

*State and local laws differ, and additional notifications may be applicable depending on laws and the situation. Public health agencies should be prepared by understanding reporting requirements prior to an outbreak.

Chapter 3 Planning & Preparation

3.2 Outbreak Response Team

3.2.1 Overview

Prior to an outbreak, it is helpful for a public health agency to establish who will respond when an HAI/AR outbreak is detected; this is the outbreak response team. At its most basic level, an outbreak response team may consist of a single epidemiologist; larger or more complex events may need several staff members, including a more senior medical epidemiologist, an infection preventionist, and other personnel with specialized expertise. A scalable response may require the staff involved in the outbreak response to adapt to different roles during the investigation. Personnel designated as part of an outbreak response team should receive ongoing training in outbreak investigation and response.

Roles and responsibilities for each team member should be clear and assigned early. Although public health agencies may designate roles in protocol documents and assign individuals to fill each role as the team is assembled at the beginning of a response, these roles should be flexible throughout the course of an outbreak investigation, and team members may fill more than one role.

3.2.2 Roles of Team Members

An entire outbreak response likely involves multiple entities (e.g., one or more public health agencies and one or more healthcare facilities), each with their own response team. The overall coordinating agency may serve as a traditional lead or may function as a facilitator and convener. Regardless of which agency is in the lead, each team must appreciate the importance of considering multiple points of view across the various entities involved in the response.

Public health team members, their roles, and their primary responsibilities are described in this section. The purpose is to make it easy for public health agencies to quickly assign roles to team members and ensure that key tasks are covered; however, responsibilities can be modified and transferred to other team members as needed.

Consider designating a single point of contact for the public health team to communicate with other involved entities. The point of contact can be any team member, but consideration should be given to keeping the point of contact consistent throughout the investigation. Points of contact should have excellent communication skills and experience working in or with healthcare facilities.

3.2.2.1 Team Leader

During any response to a suspected outbreak, a team leader should be designated. In small outbreaks, one epidemiologist may be sufficient to respond; however, as soon as additional team members have been added, it is helpful to have a clear team leader. During multi-agency responses, it is similarly helpful to designate an overall lead, or coordinating, agency. The team leader at the coordinating agency may hold the primary role of facilitator and convener, with other entities having their own team leaders for their jurisdiction or facility. The team leader should make a concerted effort to understand the roles and expertise of members of the team and those of members of other teams working across other entities. The team leader sets the tone for the investigation and should be an individual who can maintain a calm demeanor during stressful situations.

Responsibilities:
Responsibilities of the team leader include the following: overall organization; setting priorities; leading meetings and conference calls, including preparing clear agendas; coordinating all activities associated with the investigation; assigning roles and tasks to team members; modifying team roles and requesting additional staff when needed; coordinating messaging to other involved agencies, communication staff, and the outbreak response team; ensuring open communication among entities including communication with agency decision-makers; and ensuring each team member and involved agency has needed information.

3.2.2.2 Epidemiologists

Epidemiologists usually have a central role in healthcare outbreak investigations. One or more epidemiologists may be needed to support the outbreak response team with sound epidemiologic approaches—ranging from descriptive epidemiology to complex analytic methods—to help determine possible modes and sources of transmission and to rapidly implement control measures.

Responsibilities:
Epidemiologists identify cases; develop case definitions; develop hypotheses and strategies to test them; obtain information about the cases and other patients via interviews, medical record reviews, and observations; perform descriptive analyses using collected data; plan epidemiologic studies; analyze investigation data using statistical analyses; present results to make interpretations; coordinate testing of specimens and samples; and coordinate with other team members.

3.2.2.3 Infection Preventionists

HAI/AR outbreaks are unique in that infection control breaches of some kind are often the cause of, or contributors to, an outbreak. Infection preventionists (IPs) have specific skills and training related to the prevention of transmission of infections in the healthcare setting. IPs are adept at assessing care practices and the environment of care; many IPs have clinical experience and can contribute additional knowledge and context during an investigation.

Responsibilities:
An IP obtains and interprets information about the healthcare facility and cases related to infection prevention practices, reviews and interprets policies and procedures, performs observations on site to identify infection control gaps or breaches, provides infection control recommendations to the team and the healthcare facility to stop disease transmission, and provides additional clinical context during the investigation.

3.2.2.4 Laboratorians

Laboratorians provide expertise and advice related to the performance of laboratory testing. Laboratorians may also contribute specialized knowledge related to environmental reservoirs of HAI/AR pathogens. It is best practice for laboratorians to attend team meetings and be included in overall communications (not limited solely to laboratory aspects of the investigation). Excellent communication ensures that epidemiologists understand laboratory testing, and laboratorians should be kept informed about the epidemiologic investigation.

Responsibilities:
Laboratorians advise the outbreak team on appropriate laboratory testing methods, including the collection,

handling, storage, and transport of clinical or environmental specimens; test clinical specimens or isolates; analyze environmental samples when obtained; interpret and report results; communicate laboratory testing methods and results; and maintain chain of custody when required. See Chapter 6 for more information.

3.2.2.5 Additional Team Members

Administrative staff: Planning efforts should include support personnel to make phone calls, answer inquiries from concerned members of the public, perform data entry and assist with information management, and conduct other administrative work.

Statistician: A statistician should be added to the team when advanced epidemiologic methods are employed that require additional analytic skills. Some public health agencies may not have a statistician available. Consider requesting help from other agencies when additional statistical help is needed.

Subject matter experts: Planning efforts should include identifying subject matter experts who can be called upon to assist with commonly encountered assessment needs that arise as part of healthcare outbreak investigations. Examples include engineers or environmental scientists with experience evaluating healthcare facility ventilation or water systems.

Public information officer: Public information officers (often referred to as "PIOs") and communications experts should be involved early as a part of the outbreak response team when an outbreak is anticipated to be large enough to gain media attention; when communication assistance is needed among agencies; when developing messaging, such as for facilities or for the public; or if other communication needs occur.

Legal support: Like public information officers, legal staff should be involved early as a part of the outbreak response team when legal questions are anticipated to arise. Legal staff can help with interpreting public health authority and assist in interactions with legal staff in other agencies and healthcare facilities.

Emergency preparedness: When a response to an outbreak or infection control breach requires large amounts of agency resources, when media attention can occur, or when establishment of an incident command system (ICS) is under consideration, public health agencies should consider involving emergency preparedness staff. Emergency preparedness staff can provide expertise in the emergency response and the ICS as well as additional logistical support with resource requests (e.g., staffing or supplies).

3.2.3   Outbreak Response Team Model Practices

3.2.3.1 Outbreak Response Unit
Entities that routinely respond to healthcare outbreaks should establish a team that can be dedicated to that purpose. Ideally, outbreak response team members will be skilled in outbreak responses and have knowledge of healthcare settings. Team members may have other responsibilities when outbreaks are not occurring, particularly in smaller agencies. Having a dedicated team allows for team members to gain experience collaborating with each other and ensures consistency across investigations.

3.2.3.2 Additional Support
In large-scale events, it may be necessary to expand the outbreak team to include additional support for medical record reviews, interviews of patients, or other tasks such as data entry. Identification in advance of additional people to assist with these tasks can help an investigation proceed rapidly without taxing agency resources. Additional persons to be identified could include staff within other areas of an agency (some may have medical record review experience or experience in interviewing patients) or personnel from other organizations (e.g., medical students, residents and fellows, or public health students) with minimal levels of expertise. Inclusion of trainees in an outbreak response can be beneficial for both the team (helping with staffing and resource limitations) and trainee (providing valuable experience). Develop just-in-time training for additional support staff and provide directed training to allow for rapid incorporation of these staff members into the team.

Public health agencies should identify possible external sources of expertise to assist the outbreak response team when such sources are not internally available. Part of planning includes identification of gaps in expertise within an agency and identification of other entities that have this expertise; often needed expertise may be found at the state health department or CDC. Building relationships with a variety of healthcare facility and community partners can be advantageous when additional expertise is needed beyond the capacity of public health, particularly in areas not typically found within public health agencies, such as respiratory therapy, industrial hygiene, and pharmacy, to name a few.

3.2.3.3 Outbreak Response Plans and Protocols
Outbreak response plans should be scalable, adaptable, and flexible, so that they can be implemented when an outbreak is limited to a few cases and rapidly expanded if the scope of the outbreak broadens. Plans should be flexible, so that they can be used in any healthcare setting or unit, including specialized units within facilities. It is helpful to have general outbreak response plans as well as pathogen- or condition-specific response protocols for the types of outbreaks that are seen frequently. Established plans and protocols allow for a rapid response, provide support for less-experienced team members, and offer consistency across similar outbreaks.

Plans can include contact lists (including lists of outbreak response team members and people within the agency to inform, outside agency contact lists, and contact lists for additional support team members), steps to follow during an outbreak, scientific publications and other key reference texts, draft agendas for meetings and conference calls, draft emails for situational updates, medical record review forms, interview forms, on-site facility infection control assessment tools, laboratory testing information, and any other pieces that are common across outbreaks. Additional information about assembling documents and toolkits for a healthcare outbreak response are described in section 3.3 Resources.

3.2.3.4 Training for the Team
Didactic and operational training for the team should be provided for all personnel who may be tasked with

responding to an outbreak on a regular basis. Consider training on agency protocols, specific subjects (e.g., pathogens seen routinely, healthcare settings commonly worked with, and infection control practices), and general outbreak response. Since the healthcare outbreak response is specialized, public health staff responding to outbreaks should have training or experience in healthcare settings and understand the roles of healthcare facility staff, in particular infection preventionists.

Consider shadowing opportunities within facilities when available and internal training sessions for staff who have never worked in a healthcare setting given by staff members who have. Staff unfamiliar with an outbreak response in healthcare settings can be paired with more experienced and knowledgeable staff members, when needed, to provide on-the-job training. Specific just-in-time training can also be conducted when a new situation is encountered or it is necessary to add team members with less experience to an ongoing outbreak response. Training in the ICS can also be helpful (the ICS is discussed later in this chapter). Additional training is available for public health staff from a variety of resources; some examples relevant to a healthcare outbreak response are listed in Box 3.1.

Conducting simulated exercises is another way to prepare for an outbreak response. Exercises may be discussion-based or operations-based.[7] Examples of discussion-based exercises include seminars, workshops, tabletops, and games simulating operations—many of which can be found online. Operations-based exercises include drills, functional exercises, and full-scale exercises. Regional training conducted with multiple agencies can help identify problems that may arise during outbreaks involving multiple entities.

3.3 Resources

Part of preparing for the investigation of an HAI/AR outbreak is assembling the necessary resources—supplies, equipment, and personnel—to support the outbreak response team and ensure that everything needed for the investigation and response is readily available. In this section we describe resources that can be assembled prior to an outbreak.

Personnel resource needs were discussed in the previous section. The following lists of equipment, supplies, documents, and reference materials will help public health agencies identify resources in preparation for outbreak

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Box 3.1 | Selected Training Resources

● Infection control training through CDC can be found at the following links:
  ○ CDC/STRIVE Infection Control Training: https://www.cdc.gov/infection-control/hcp/training/strive.html
  ○ Project Firstline: www.cdc.gov/infectioncontrol/projectfirstline/index.html
  ○ Infection prevention training for nursing homes and assisted living facilities: https://www.cdc.gov/long-term-care-facilities/hcp/training/index.html
● Healthcare epidemiology trainings offered by the Society for Healthcare Epidemiology of America (SHEA) can be found at learningce.shea-online.org
● SHEA/CDC Outbreak Response Training Program (ORTP) can be found at https://learningce.shea-online.org/content/sheacdc-outbreak-response-training-program-ortp
● Infection prevention training resources offered by the Association for Professionals in Infection Control and Epidemiology (APIC) can be found at https://apic.org/education-and-events/online-learning.
● Manufacturers of medical devices sometimes offer free or low-cost online or in-person training in device-specific reprocessing and infection prevention measures, such as online courses related to endoscope reprocessing.

investigation; outbreak training should include methods to obtain resources specific to a particular outbreak as needed during the investigation.

3.3.1 Equipment and Supplies

List of equipment and supplies to consider in preparation for an outbreak response:

- Communication equipment: Consider the capability and equipment for conference calls and online meeting platforms that can support large numbers of users.
- Electronic equipment: Computers, including laptops for fieldwork as well as needed software (e.g., data entry and statistical programs), should be available in advance, and portable printers can be considered. Also consider the need for secure internet access; a secure personal hotspot can be helpful.
- Data storage and transportation devices: An encrypted, portable, data storage device (e.g., an encrypted thumb drive) can help facilitate secure information sharing of electronic files too large to be emailed.
- Photography: It can be helpful to take photos during a field investigation. Ideally, personal cell phones should not be used. Be aware of your agency's policy for taking photographs or shooting videos during an outbreak. In general, avoid including people in photos unless permission has been obtained; consult with the healthcare facility about applicable policies. If photographing the environment of care, ensure that photographs do not contain identifying information. Educate personnel about policies for producing, storing, and sharing photographs or videos.
- Laboratory supplies: Consider what will be needed depending on the specimens to be collected, including appropriate specimen collection materials, containers, and transport materials (e.g., coolers and ice packs). Ensure appropriate shipping materials are available when needed. Prior to collecting samples, consultation with laboratory experts at the testing laboratory is advised. Environmental sampling should only be considered under specific conditions; in Chapters 5 and 6 we discuss additional considerations for environmental testing.
- Specialized instruments for the assessment of the environment of care, such as

  - Ultraviolet gel and a portable black light device to help evaluate environmental cleaning
  - Flutter strips, smoke tubes, or velocimeters for evaluating positive or negative air flow
  - Moisture meters to detect moisture in dry wall following exposure to water leaks

  Many acute care facilities have these instruments available, but public health agencies may find these items useful if assessing the environment of care in other healthcare settings.

3.3.2 Outbreak Investigation Documents and Toolkits

As noted in section 3.2.3, forms, information sheets, tools, plans, and protocols can be created in preparation for an outbreak response and modified as needed for specific situations. Public health agencies may consider developing outbreak investigation protocols for specific pathogens or settings, reflecting national guidelines while taking into account other considerations including local epidemiologic conditions. Information sheets, sample patient letters, and any other materials intended for dissemination to the public should be easy to read and understand, with clear instructions for ease of implementation. Public health agencies can develop tools in advance that healthcare facilities can use to report outbreaks and respond to informational needs from public health agencies. Likewise, it may be useful to establish protocols to guide involvement of communication teams and leadership as well as to advise how to notify external partners, patients, and the public.

Outbreak investigation documents to consider in preparation for an outbreak response include the following:

- Outbreak intake forms, which may be general or disease-specific
- Laboratory test requisition forms
- Standardized outbreak line lists or a database to collect case data
- Forms to assess adherence to infection prevention and control measures (e.g., Infection Control Assessment and Response [ICAR] tools and checklists)[8,9]
- Patient interview forms
- Staff interview forms

- Medical record review forms
- Facility maps
- Timeline templates
- Line-list templates and samples
- Template emails for information gathering
- Template meeting or conference call agendas
- Template letters of recommendation that public health agencies can use when recommending interventions in writing to healthcare facilities, including infection control recommendations
- Template letters to patients (e.g., letters for patient notifications)
- Templates for final outbreak reports and after-action reports
- Talking points on common pathogens or outbreak types for media inquiries
- Patient information sheets

3.3.3   Reference Materials

It is not possible to compile specific references for every outbreak that may be encountered. Having some common reference materials on hand in advance of an outbreak, however, can save the team response time. Reference materials to consider reviewing or compiling in preparation for a healthcare outbreak response include the following:

- CORHA Resources and Products for Healthcare Outbreak Response: www.corha.org/resources-and-products/
- CDC HAI prevention toolkits: https://www.cdc.gov/healthcare-associated-infections/php/toolkit/index.html
- CDC resources for Outbreak Investigations in Healthcare Settings: https://www.cdc.gov/healthcare-associated-infections/about/outbreak-investigations-in-healthcare.html
- CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) infection control guidance documents: www.cdc.gov/infectioncontrol/guidelines/index.html
- Latest version of the American Public Health Association's Control of Communicable Diseases Manual[10]

- Selected resources from federal regulatory agencies (found in Box 3.2)
- Published medical literature specific to commonly encountered outbreaks
- Resources compiled from outbreaks previously investigated by the agency

3.3.4   Tracking Time and Resources

Public health agencies should consider tracking time and resources during anticipated large-scale investigations. When processes are set up in advance of a response, tracking staff time and resources can be implemented rapidly, providing valuable information for future outbreaks and resource allocation.

3.4 Records Management

3.4.1   Overview

A tremendous amount of information can be collected during an outbreak response. Information needs to be collected and managed systematically to allow for easy access, analysis, and interpretation.

3.4.2   Records Management Model Practices

3.4.2.1 Information Collection and Sharing
Standardized data collection forms (paper or electronic) can help ensure that data are collected uniformly and systematically. If forms are not already developed ahead of an outbreak, they should be developed before data collection. Standardized forms can be modified from those used in previous outbreak investigations. Types of data collection forms include medical record review forms, patient interview forms, and healthcare facility staff interview forms. Staff collecting data should be trained in the use of forms to ensure data are collected in a consistent and appropriate manner (see section 3.8.1, Legal Preparedness, Authorities, and Litigation).

Forms, data, and information should be shared among team members in a secure manner. Methods for sharing information and types of information to be shared across agencies should ideally be determined prior to an

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Box 3.2 | Selected Resources from Federal Regulatory Agencies

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Centers for Medicare & Medicaid Services (CMS)
- Conditions for Coverage (CfCs) & Conditions of Participation (CoPs) (health and safety standards including infection control) that healthcare organizations must meet to begin and continue participating in Medicare and Medicaid programs: www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs

Food and Drug Administration (FDA)
- MedWatch Online Voluntary Reporting Form: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
- Medical Device Recalls: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls
- MAUDE — Manufacturer and User Facility Device Experience: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
- National Drug Code Directory: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Environmental Protection Agency (EPA)
- Selected EPA-Registered Disinfectants: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
- Pesticide Product and Label System (PPLS): https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1

Occupational Safety and Health Administration (OSHA)
- Healthcare Standards and Enforcement: https://www.osha.gov/healthcare

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outbreak. Public health agencies should be aware that each entity involved in an outbreak response may have its own policies and limitations with respect to methods for sharing information (e.g., messages sent via encrypted email and/or shared documents on a secure website), and it is best practice to have several options available for sharing information to allow for flexibility.

3.4.2.2 Data Management and Investigation Tracking
Standardized databases and line lists should be used to collate data during an outbreak. General databases and line list templates can be developed ahead of time and standardized tools used in previous outbreaks can be modified. Data should be entered as soon as possible to allow for rapid interpretation and analysis. Identify software tools to be used to analyze outbreak data (e.g., Epi Info, SAS, or R) and have staff who are trained to use these tools. Ensure data are routinely backed up and kept in a secure environment.

Each investigation, whether it involves a detected cluster, suspected or confirmed outbreak, AR containment, infection control breach, or other sentinel event, should be tracked in an information management system or database. The investigation tracking system should be flexible to accommodate the various types of events and provide information to allow authorized users to do the following[3]:

- Summarize overall investigation findings
- Evaluate the effectiveness of local reporting requirements
- Inform prevention efforts by identifying facilities, settings, and issues that may benefit from proactive prevention
- Inform prevention and response guidance and tools
- Understand local resources needed for an outbreak response

A best practice for public health agencies and larger healthcare facilities or systems is to use an outbreak investigation tracking system. CORHA has developed an HAI/AR Outbreak Investigation and Response Tracking System and associated data dictionary for this purpose, available at www.corha.org/resources/corha-hai-ar-outbreak-and-response-tracking-system/. HAI/AR programs receive specific guidance on response tracking from CDC as part of the ELC.

Information that can be captured in this type of tracking database includes the following: intake information (entity reporting, dates of interest, and basic description of the situation), healthcare facility information, public health agency information, investigation information (dates of testing and onset, case definition, numbers and characteristics of cases, investigation methods, and suspected source), on-site visits conducted, laboratory information, control measures implemented, and summary and conclusions.

3.5 Communication

Effective communication is one of the most essential elements for a successful outbreak investigation. It is essential that there be processes in place for communication among the outbreak response team members, between the team and leadership within the agency, among involved agencies, with the healthcare facility or facilities involved, and with media, patients, and the public. To make communication as smooth as possible, prepare in advance and consider the following:

- Establish communication best practices for your outbreak team; strive for daily email updates or calls, with the responsibility for organizing this assigned to one team member selected at the start of the investigation.
- Take partners' needs into account when sending external updates, including those of the involved facility, regarding frequency of communication, level of information, and content (e.g., summaries of findings to date).
- Develop guidelines for when to involve public information officers and communication experts, emphasizing the need to involve them as early as possible.
- Designate an outbreak response team member as the point of contact for each communication pathway.

- Create and use contact lists for partners and personnel; in some cases, contact lists can be developed in advance.
- Have clear agendas during meetings and calls; develop template agendas and meeting invitations that include an agenda; and follow up with meeting minutes and/or a summary of key action items.
- Do not underestimate the importance of ongoing discussions during the investigation, either in person or via conference calls. It is extremely helpful to have scheduled meetings (in person or by calls) during the investigation to make sure communication pathways are established and partners are kept up to date.
- Develop procedures for presentations and publications, including procedures for early discussions internally and with partners regarding leads for any reports, papers, or other products.
- Establish mechanisms for obtaining input and opinions from leaders in other communicable disease disciplines, such as foodborne and vaccine-preventable diseases, who can provide useful ideas for how to approach communications during an outbreak investigation.
- Plan regular meetings across disciplines and among healthcare partners as part of the preparation; this can aid the outbreak response later.

3.6 Escalation

3.6.1 Overview

The public health outbreak team should periodically assess the need for obtaining additional assistance and escalating the response. Internally, there should be a communication protocol in place that includes triggers for notifying leadership and involving additional expertise (e.g., communication, emergency response, and legal expertise).

Thresholds for escalation to another agency should be considered in advance. Conversations with leadership and other internal experts can be helpful ahead of a possible escalation; they should involve preparing and educating leadership about the general course of an HAI/AR outbreak response and discussing when an outbreak may require involvement of outside agencies.

Leadership should also be knowledgeable about CDC's Epi-Aid request process. An Epi-Aid is an investigation of an urgent public health problem such as infectious or noncommunicable disease outbreaks, unexplained illnesses, or natural or manufactured disasters. When a public health authority, usually the state epidemiologist, requests assistance from CDC, an Epi-Aid allows rapid, short-term (1–3 weeks), generally on-site technical assistance by Epidemic Intelligence Service (EIS) officers and other CDC subject-matter experts. The focus of an Epi-Aid investigation is to assist partners in making rapid, practical decisions for actions to prevent and control the public health problem.[4]

3.6.2   When to Ask for Help

A cardinal rule for all HAI/AR outbreak response teams: Ask for help earlier rather than later. A seemingly small or local outbreak may signal a much larger problem. Preparations should include discussions internally regarding when the agency should seek help from another agency.

Consider asking for help when
- The pathogen is novel or is of high consequence, or transmission appears to occur by novel means.
- The scale of the outbreak seems likely to overwhelm agency resources.
- Initial remediation attempts fail.
- The outbreak is known or suspected to affect multiple counties, states, or countries, or expands beyond the original jurisdiction.
- The investigation points to a regulated or widely distributed medical product.
- The nature of the outbreak (e.g., agent, affected population, or scale) or response is beyond the experience of the agency staff.
- Specific technical support or expertise is needed.
- Specialized laboratory services or support is needed.

3.6.3   How to Obtain Help

Knowledge of how to obtain help when needed is a key aspect of a public health agency's preparation and planning for a healthcare outbreak response. To receive prompt assistance and ensure that adequate patient protections are quickly put in place, healthcare facilities should be reminded of requirements and thresholds for reporting potential outbreaks as soon as the outbreak is suspected and not wait for an outbreak to grow.

In general, public health agencies should begin escalation by requesting assistance from the public health agency at the next jurisdiction level (e.g., local public health agencies should contact the state and state public health agencies should contact CDC). State public health agencies have communicable disease or HAI/AR programs that can be contacted directly; if unable to locate contact information directly, call the general agency number or the 24/7 on-call person for the agency. Public health agencies can contact CDC for technical assistance related to healthcare outbreak investigations via email (haioutbreak@cdc.gov) or by phone using the CDC 24/7 emergency response number (800-CDC-INFO).

3.7   Incident Command System (ICS)

Originally developed in the 1970s to coordinate activities to control wildfires, the Incident Command System (ICS) is a scalable structure that states may adapt to meet their needs during an outbreak, including within a single jurisdiction. The system has been expanded and integrated into the Federal Emergency Management Agency's (FEMA's) National Incident Management System (NIMS) to aid intra-agency and interagency coordination, especially during large-scale emergencies that involve multiple jurisdictions. The ICS features a clearly defined chain of command with common nomenclature for key management positions, defined management sections, and a modular organizational structure.

The ICS uses specifically defined emergency response function roles. Public health agencies at the local and state levels may use the ICS as part of an all-hazards plan to mitigate threats to health and safety. Federal agencies are required by executive order to use the ICS to address outbreaks that are considered public health emergencies, so that all relevant federal agencies, as well as state and local governments, are appropriately coordinated and connected during emergencies. The CMS Emergency Preparedness Rule[11] has mandated that 17 different types of healthcare organizations develop all-hazards plans, listed in Box 3.3.

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> **Box 3.3 | Types of Facilities Required by CMS to Develop Emergency Preparedness Plans**[11]
>
> 1. Hospitals
> 2. Religious Nonmedical Health Care Institutions (RNHCIs)
> 3. Ambulatory Surgical Centers (ASCs)
> 4. Hospices
> 5. Psychiatric Residential Treatment Facilities (PRTFs)
> 6. Program of All-Inclusive Care for the Elderly (PACE) Organizations
> 7. Transplant Centers
> 8. Long-Term Care (LTC) Facilities
> 9. ntermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
> 10. Home Health Agencies (HHAs)
> 11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
> 12. Critical Access Hospitals (CAHs)
> 13. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
> 14. Community Mental Health Centers (CMHCs)
> 15. Organ Procurement Organizations (OPOs)
> 16. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
> 17. End-Stage Renal Disease (ESRD) Facilities

Most HAI/AR disease outbreak investigations do not require formal activation of the ICS, but elements of it are frequently utilized in outbreaks. For larger investigations or investigations that may lead to media attention, early use of the ICS can be beneficial by providing additional structure and support to the outbreak response team.

3.8 Other Aspects of Preparation

3.8.1 Legal Preparedness, Authorities, and Litigation

Agencies should understand their legal authority to conduct an outbreak investigation and steps that can legally be taken to halt an outbreak; all relevant laws related to disease surveillance, reporting (including reporting of outbreaks), detection, investigation, and control activities should be understood in advance.[6,12] Specific authority and the basis for that authority,

particularly when working in healthcare facilities, varies among states and jurisdictions; staff involved in outbreak investigations should understand the authority of their specific agency. If there are legal agreements that need to be in place for information sharing across agencies, these should be identified and put into place ahead of an outbreak. The agency should have legal staff available to provide advice and to join the outbreak response team when needed.

Outbreaks can result in litigation and have broad financial and public relations implications for affected facilities.[13] As a result, there may be increases in scrutiny and the number of stakeholders interested in the investigation. There may be increased pressure to investigate rapidly or implement necessary control strategies quickly. In addition, public health records frequently are the subject of Freedom of Information

Act requests. Agencies should prepare their outbreak response staff regarding procedures for documenting the steps taken in an investigation and advise them to exercise care and discretion in using emails and other communications, recognizing that investigation records might become publicly available or used as part of litigation proceedings.[13]

3.8.2 Ethics

Ethical dilemmas may arise during investigations of outbreaks or infection control breaches, particularly regarding decisions about patient notification. In advance of an outbreak investigation, public health agencies should consider what standards and conventions to apply as well as criteria for arranging consultations and obtaining guidance. Although it is not always possible to anticipate ethical questions in advance, agencies should consider establishing guidelines in advance. For example, agencies can consider what questions may need to be addressed to make the decision to notify patients about an outbreak at a healthcare facility or notify patients about deficient medical care practices or possible infection risks (e.g., bloodborne pathogens) following an infection control breach.

3.8.3 Privacy

Public health agencies should be familiar with laws related to protecting the confidentiality of patients and healthcare facilities. Protocols similar to those used in the collection of routine surveillance data may guide records management protocols that are compliant with the Privacy Act, the Federal Information Security Modernization Act (FISMA), the Healthcare Insurance Portability and Accountability Act (HIPAA), and state laws. Plan to collect the minimum amount of data needed. The privacy rule allows healthcare entities to share protected information directly with public health agencies that are legally authorized to receive reports for the purpose of controlling disease, injury, or disability.[14,15]

Methods aimed at maintaining the confidentiality of information collected during the outbreak should be instituted and adhered to consistently. Examples of methods to maintain confidentiality include the

following: assigning a unique non-personal identifier to patients (such as when transporting forms with medical information or when sharing information with agencies that do not need personal identifiers); encrypting emails when confidential information is shared between agencies; and limiting the number and type of personal identifiers collected as far as possible. Identifiers include direct identifiers (such as name, date of birth, and address) and indirect identifiers (such as dates of admission and discharge).[14,15]

Protection or disclosure of the name of a healthcare facility depends on state laws. In general, when there is a public health need to share the name of the healthcare facility in order to protect patients and the public, this need takes precedence.

3.8.4 Permissions and Approvals

The outbreak response team should consider if there are permissions and approvals that need to be obtained within their agency or across agencies. Understanding required permissions and approvals ahead of an outbreak can reduce miscommunication and speed up a response. Make sure there is an understanding with leadership within the agency of any necessary permissions and approvals.

Public health agencies should explore options and approaches for accessing facility medical records in advance of outbreaks. Often access to an electronic system of health records takes time to acquire, and valuable time can be saved if members of the outbreak team already have access; this accommodation may already be in place due to public health surveillance activities. In some cases, access may be given at the level of the health system. Gaining access to facility electronic medical records can be challenging but worth the initial effort in advance of, or very early in, an outbreak investigation.

3.9 Planning for Recovery and Follow-Up

3.9.1 Overview

Public health agencies should establish processes for completing an outbreak investigation, ensuring that gap

mitigation is maintained, and capturing lessons learned for applying them to future outbreaks. See Chapter 5 for additional details. When recovery and follow-up are planned ahead of an outbreak, information related to these activities can be recorded during the course of the outbreak investigation, saving time when wrapping up investigations.

3.9.2 Recovery and Follow-Up Model Practices

Model practices to plan for recovery and follow-up include the following:

- Establish criteria at the start of an outbreak to determine actions that must happen, or endpoints that must be met, before de-escalating enhanced surveillance or prevention measures. As the outbreak evolves, these criteria can be modified. In some situations, general criteria can be established ahead of an outbreak.

- Ensure that lessons learned are recorded throughout the outbreak investigation, and that these are available for informing and improving future outbreak response activities. Establish procedures for process improvement based on lessons learned.
- Identify final outbreak report templates and processes ahead of, or early in, the outbreak and consider populating information as the investigation progresses. This enhances recall and saves time at the end of an investigation.
- Consider after-action discussions following the investigation to identify successes, challenges, and any gaps that can be mitigated. Discussions should include agencies, facilities, providers, and other stakeholders involved in the response. It is often helpful to have discussions moderated by someone with expertise in facilitation. Preparation steps can include template after-action reports, template agendas for after-action meetings, and identification of facilitation experts.

CORHA Keys to Success

Developing Relationships Prior to an Outbreak

An outbreak is not the time for first introductions. Partners within the public health and healthcare community should recognize the importance of mutually supporting capabilities during outbreak investigations.

Relationships

- Relationships among public health agencies, regulatory agencies (e.g., state survey agency and state licensing boards), member organizations, law enforcement agencies, and healthcare facilities should be developed at and across local, state, and federal levels.
- Public health and healthcare facility relationships can be developed by attendance of public health

agency staff at local meetings such as the Association for Professionals in Infection Control and Epidemiology (APIC), holding educational events or conferences for healthcare facility partners, and attendance and presentations at facility-offered events such as grand rounds.

Continued on following page.

CORHA Keys to Success

Relationships

- Public health agencies should collaborate with local healthcare industry associations such as the local hospital association, long-term care association, quality improvement organization, and professional societies. These organizations possess valuable knowledge from their stakeholders and can assist public health agencies in outreach efforts.
- Relationships are strengthened when public health agencies have established procedures for working with other agencies and organizations during an outbreak response, and when public health staff understand the roles of their agency and partner agencies. Public health agencies can also develop tools to help healthcare facilities respond to public health requests during an outbreak response.
- Use local epidemiology, newly published guidance, and lessons learned from previous outbreak investigations to identify opportunities for outreach.
- Relationships with healthcare facilities are strengthened when public health understands and acknowledges the expertise of the healthcare facility. One way to accomplish this is to ask for assistance from facilities or providers with expertise in areas in which public health is working.

Communication

- Procedures should be in place that describe general communication plans during an outbreak among involved partners. These procedures can be modified or specified in greater detail for individual outbreaks. Established communication plans can ensure clear communication is present from the initiation of an outbreak response.

- Plan for frequent communication among the outbreak response team and involved agencies; it is better to over-communicate than under-communicate. Prepare for communication using a variety of methods, including in-person or virtual meetings, conference calls, and email updates.
- Establishing methods and schedules for communication with facilities at the first stages of an investigation can help alleviate trying to communicate during busy schedules.
- Outbreak team members should practice excellent communication skills. Consider effective communication as one aspect of team member training in advance of an outbreak.

Flexibility

- Public health can assess the needs of healthcare facilities and provide services in advance (e.g., tools for outbreak response and advanced laboratory services). Flexible collaboration at all stages of preparation will enhance relationships and facilitate a nimbler outbreak response if the investigation changes course.
- All involved agencies and healthcare facilities should understand that the outbreak investigation can change course quickly, and staff should remain flexible during an outbreak response. Preparation should not be so rigid that this need for flexibility is overlooked.

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